



ENZYMATIC THERAPY

MANUFACTURED

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April 24, 2004

INTEGRATIVE THERAPEUTICS INC.™

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Wilsonville, OR 97070
P: 503.582.8386 → F: 503.582.0467

ENZYMATIC THERAPY®

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825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 → F: 888.570.6460 (Enzymatic)
P: 920.469.9099 → F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

MAY 1 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards Fruit and Veggie 5™	Fruit & Veggie 5 not only provides valuable fiber often lacking in the low-carb diet, but beneficial nutrients equivalent to the recommended intake of five fruits and vegetables per day.*	Dietary fiber, Vitamin A (as beta-carotene), Vitamin C (Ascorbic acid), Psyllium (Plantago ovata) Husk, Pectin (from citrus fruit) Proprietary PhytoRedoxin™ Blend: Lutein 5% (from Calendula officinalis), lycopene, and quercetin

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/24/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

975 0162

LET

14047

Body Rewards Fruit and Veggie 5 10e



ENZYMATIC THERAPY

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April 25, 2004

INTEGRATIVE THERAPEUTICS INC.™

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Dietary fiber plays many important roles in health, including providing bulk of feces, which aids elimination and supports regular bowel movements.* It also supports metabolic activity in the body by inhibiting cholesterol absorption and slowing glucose absorption in the small intestine.*	Dietary fiber, Vitamin A (as beta-carotene), Vitamin C (Ascorbic acid), Psyllium (Plantago ovata) Husk, Pectin (from citrus fruit) Proprietary PhytoRedoxin™ Blend Lutein 5% (from Calendula officinalis), lycopene, and quercetin

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/25/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

Body Rewards Fruit and Veggie 5 11c



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Dietary fiber has also been studied for its support of the immune system and healthy white blood cells.*	Dietary fiber, Vitamin A (as beta-carotene), Vitamin C (Ascorbic acid), Psyllium (Plantago ovata) Husk, Pectin (from citrus fruit) Proprietary PhytoRedoxin™ Blend: Lutein 5% (from Calendula officinalis), lycopene, and quercetin

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By: 


Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/25/04

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Sincerely,


Michael P. Devereux
Chief Financial Officer

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ENZYMATIC THERAPY

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what Better feels like™

April 26, 2004

Office of Nutritional Products, Labeling &
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Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Dietary fiber supports digestion by helping the colon become more acidic, thus supporting the growth of beneficial microflora in the intestines.*	Dietary fiber, Vitamin A (as beta-carotene), Vitamin C (Ascorbic acid), Psyllium (Plantago ovata) Husk, Pectin (from citrus fruit) Proprietary PhytoRedoxin™ Blend: Lutein 5% (from Calendula officinalis), lycopene, and quercetin

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

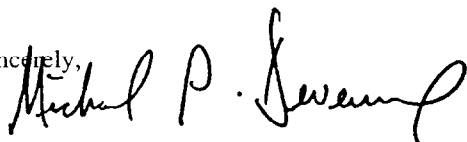
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer



ENZYMATIC THERAPY INCORPORATED

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April 26, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Beta-carotene can act as an antioxidant and help boost the immune system.*	Vitamin A (as beta-carotene)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

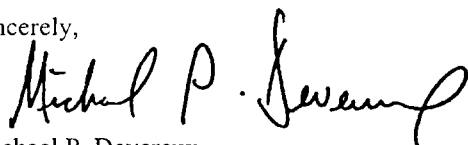
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

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April 27, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Supports immune function, cardiovascular health, and has antioxidant properties.*	Vitamin C (Ascorbic acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

4/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Financial Officer



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April 27, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Psyllium husk is a rich source of concentrated soluble fiber that supports healthy intestinal function.*	Psyllium (Plantago ovata) Husk

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Often used in laxation, psyllium husk provides intestinal lubrication for ease in elimination.*	Psyllium (Plantago ovata) Husk

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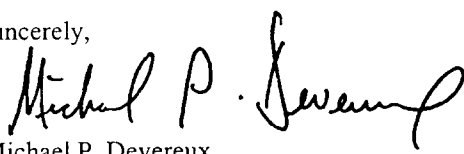
By: 
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/27/04

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Sincerely,


Michael P. Devereux
Chief Financial Officer



ENZYMATIC THERAPY INCORPORATED

What *Better* feels like.
April 28, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	In studies, psyllium husk has been shown to absorb up to fourteen times its weight in water and has more re-absorption ability than any other bowel-supporting fiber.*	Psyllium (Plantago ovata) Husk

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

4/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Psyllium husk also supports healthy serum lipid levels that are within normal limits, healthy blood sugar metabolism that are already within their normal limits, healthy blood pressure that is already within normal limits, healthy immune function, and intestinal microflora health.*	Psyllium (Plantago ovata) Husk

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and a middle initial "P." in between.

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Pectin from citrus fruit is a soluble fiber that has been studied for its support of immune health.*	Pectin (from citrus fruit)

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By: _____

Robert Doster

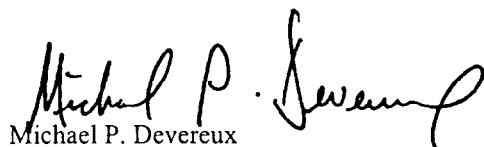
Title: Senior Vice President of Scientific Affairs

Date: _____

4/29/04

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Sincerely,


Michael P. Devereux
Chief Financial Officer

Body Rewards Fruit and Veggie 5 20c



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Body Rewards Fruit and Veggie 5™	Lutein: It is being considered one of the most beneficial nutrients in the carotenoid group, supporting immune health and healthy colon function, as well as vision by promoting macular health.*	Lutein 5% (from Calendula officinalis)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

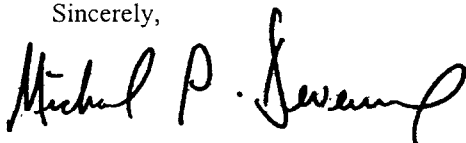
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-30-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

Body Rewards Fruit and Veggie 5 21c



ENZYMATIC THERAPY INCORPORATED

What **Better** feels like™
April 29, 2004

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas ♦ PhytoPharmica
Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 ♦ F: 503.582.0467

ENZYMATIC THERAPY™ & PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Lycopene: It has shown in scientific studies to have immune supportive properties.*	Lycopene

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By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

4/29/04

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Sincerely,

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Lycopene functions as an anti-aging antioxidant with studies linking it to prostate and cardiovascular health.*	Lycopene

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By: _____

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: _____

4/30/04

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Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Quercetin has been the subject of recent research highlighting its beneficial support for cardiovascular health.*	Quercetin

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By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/30/04

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Sincerely,

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Body Rewards Fruit and Veggie 5™	Strict adherence to a low-carb diet requires avoidance of fiber and antioxidant containing fruits and vegetables. Fruit & Veggie 5™ provides these important nutrients to help the low-carb dieter stay healthy while meeting their weight loss goals.*	Dietary fiber, Vitamin A (as beta-carotene), Vitamin C (Ascorbic acid), Psyllium (Plantago ovata) Husk, Pectin (from citrus fruit) Proprietary PhytoRedoxin™ Blend: Lutein 5% (from Calendula officinalis), lycopene, and quercetin

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Date: 4/30/04

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Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and "P." as a middle initial.

Michael P. Devereux
Chief Financial Officer